

510(k) SUMMARY

K022048

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SUBMITTED BY

Lynn Rodarti
Manager, Regulatory and Clinical Affairs
Interpore Cross International
181 Technology Drive
Irvine, California 92618
(949) 453-3200

DEC 04 2002

June 18, 2002

This summary of 510(k) substantial equivalence information is being submitted in accordance with the requirements of 21 CFR §807.92.

CLASSIFICATION, COMMON OR USUAL NAME, DEVICE NAME

Classification Name:	Appliance, Fixation, Spinal Interlaminar Orthosis
Common/Usual Name:	Spinal Interlaminar Orthosis Fixation
Product Classification:	Class II
Proprietary Name:	ICI (Occipito-Cervico-Thoracic (OCT) Rod and Plate System

PREDICATE DEVICE

The predicate device is the Summit Occipito-Cervico-Thoracic (OCT) Spinal System that is currently manufactured and distributed by DePuy AcroMed™, Inc.

INDICATIONS-FOR-USE

When intended to promote fusion of the cervical spine and occipito-cervico-thoracic junction (occiput-T3), the Interpore Cross International ICI Occipito-Cervico-Thoracic (OCT) Rod and Plate System is indicated for:

- DDD (neck pain of discogenic origin with degeneration of the disc as confirmed by patient history and radiographic studies)
- Spondylolisthesis
- Spinal stenosis
- Fracture/dislocation
- Atlantoaxial fracture with instability
- Occipitocervical dislocation
- Revision of previous cervical spine surgery
- Tumors

The occipital bone screws are limited to occipital fixation only.

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DEVICE DESCRIPTION

The Interpore Cross International ICI Occipito-Cervico-Thoracic (OCT) Rod and Plate System is a titanium system composed of rods, bone screws, hooks, set screws, nuts, cross connectors, and plates. For occipito-cervico-thoracic fusion, the occipital plate is fixed to the occiput with bone screws. The pre-bent rod is cut to the appropriate length. Bone screws are placed in the thoracic spine (T1-T3) and hooks are placed in the cervical spine. The rod is inserted and the construct is locked with screws and nuts. Cross connectors can be added to the construct.

COMPARISON TO THE PREDICATE DEVICE

The ICI OCT Rod and Plate System is similar in design to the Summit OCT Spinal System. They are both intended for the same use, specifically, to promote fusion of the cervical spine and occipito-cervico-thoracic junction (occiput-T3). Both are made from the same material, titanium. Based on this information, the ICI OCT Rod and Plate System is substantially equivalent to the Summit OCT Spinal System.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 04 2002

Wendy Spielberger
Senior Regulatory Affairs Associate
Interpore Cross International
181 Technology Drive
Irvine, California 92618-2402

Re: K022048

Trade/Device Name: OCT Rod and Plate System
Regulation Number: 21 CFR 888.3050
Regulation Name: Spinal interlaminar fixation orthosis
Regulatory Class: Class II
Product Code: KWP
Dated: September 4, 2002
Received: September 5, 2002

Dear Ms. Spielberger:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

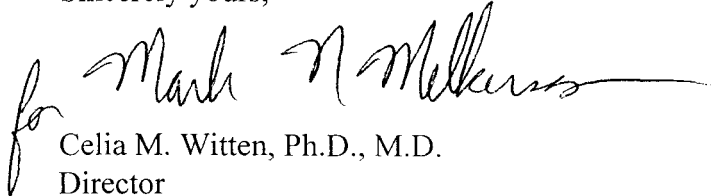
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Page 2 – Ms. Wendy Spielberger

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>.

Sincerely yours,

for Celia M. Witten, Ph.D., M.D.
Director

Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K022048

Device Name: Interpore Cross International (ICI) Occipito-Cervico-Thoracic (OCT) Rod and Plate System

Indications-For-Use:

When intended to promote fusion of the cervical spine and occipito-cervico-thoracic junction (occiput-T3), the Interpore Cross International (ICI) Occipito-Cervico-Thoracic (OCT) Rod and Plate System is indicated for:

- DDD (neck pain of discogenic origin with degeneration of the disc as confirmed by patient history and radiographic studies)
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(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____
(PER 21 CFR 801.109)

OR

Over-The-Counter Use

(Optional Format 1-2-96)

for Mark A. Miller
(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K022048